

Beyond Genetically Modified Microorganisms: Policy, Regulatory and Scientific Aspects of Using Laboratory-Trained Bacteria for Environmental Applications

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Setting the Scene

On 3 February 2026, researchers, regulators and policy specialists gathered in Brussels to examine a rapidly evolving question at the intersection of biotechnology and environmental governance: **how should we regulate and manage laboratory-trained bacteria designed to work outside the lab?**

The workshop was organised within the framework of the **Horizon Europe project NYMPHE**, bringing together partners working on innovative bioremediation approaches and their broader policy, regulatory and societal implications. It focused on microorganisms engineered not for industrial tanks or clinical settings, but for **direct interaction with natural ecosystems** — soils, waters and polluted environments. Across disciplines, speakers agreed that this shift in application challenges both traditional biosafety concepts and long-standing regulatory structures.

A unifying theme quickly emerged: the need to move beyond a narrow focus on **control and containment** and towards a broader model of **stewardship, monitoring and adaptive governance**.

From Early GMOs to Synthetic Environmental Biology

Opening the scientific discussion, **Victor de Lorenzo** (CNB–CSIC) traced the historical arc of environmental biotechnology. Many early efforts in the 1980s and 1990s focused on genetically modified bacteria designed to degrade specific pollutants in the laboratory. While scientifically promising, many of these initiatives stalled under regulatory and societal resistance as well as lack of good concepts for scaling up bioremediation interventions.

Today, the field has evolved into something far more sophisticated. Synthetic biology now enables the design of **complex genetic circuits, specialized microbial “chassis,” and multi-species consortia** tailored to perform complex environmental functions. Potential applications range from carbon capture and methane reduction to plastic degradation and soil regeneration — part of what de Lorenzo described as a new wave of **large-scale environmental biotechnologies**.

Yet he emphasized a crucial practical gap: designing a microorganism in the laboratory is only the first step. Delivering it effectively into a dynamic ecosystem — what he termed “**environmental galenics**” — remains a major scientific and technological challenge. This includes formulation, dispersal strategies, ecological integration, and long-term tracking.

Most provocatively, he argued that **complete biological containment in open environments is unrealistic**. Living organisms evolve, exchange genes and interact in unpredictable ways. Governance frameworks must therefore shift from attempting absolute control to ensuring **long-term oversight, traceability (eg through genomic barcoding or watermarking), and responsible management**.

When Innovation Outpaces Regulation

The regulatory dimension was explored by **Patrick Rüdelsheim**, who described the growing mismatch between modern biotechnology and legacy legal frameworks. Many current GMO regulations were

built around earlier generations of genetic engineering and remain heavily **process-based**, focusing on how an organism was modified rather than what risks it poses.

This can create situations where products with comparable risk profiles face vastly different regulatory burdens depending on the technique used. The result, he noted, is often **legal uncertainty and delayed innovation**, rather than improved safety.

He called for a gradual transition toward **risk-based, product-oriented oversight**, where regulatory scrutiny is calibrated to the characteristics, function and intended environmental use of the organism. Recent European efforts to tailor GMO legislation, including for GMMs used in bioremediation and wastewater treatment, may add clarity but are unlikely to deliver the fundamental breakthrough needed for future complex technological applications.

Lessons from Real-World Field Applications

A central analytic thread at the workshop was the question: *what can we learn from real-world applications of engineered organisms outside of containment?*

Providing an empirical perspective, **Emma Frow** (Arizona State University) shared insights from past field trials involving engineered microorganisms, drawing on comparative research into environmental releases.

These cases showed that **environmental and social realities often diverge from laboratory expectations**. In some instances, introduced strains declined over time, yet their functional genes persisted in local microbial communities through **horizontal gene transfer**. In others, technically successful organisms failed to be deployed because regulatory pathways proved too complex or public acceptance was lacking. An interesting finding was that endowing biological agents with genetic devices for containment does not increase the user's perception of safety.

A key conclusion was that environmental biotechnology is not just a scientific endeavour but a **socio-technical system**, where regulatory context, economic structures, governance capacity and community perceptions are as decisive as molecular design.

In her report, Frow and colleagues examined a set of case studies spanning bioremediation, biocontrol, and nitrogen fixation, revealing patterns that challenge conventional assumptions in both science and regulation:

- Containment technologies alone do not ensure environmental control. Engineered organisms interact with complex microbial communities and may persist, transfer genetic material, or influence ecosystem processes in unintended ways. In many historical trials, containment strategies (e.g., genetic safeguards) did not prevent organism spread, yet environmental function was often retained through gene transfer within native microbiomes.
- Success is socially as well as technically determined. Many engineered strains that performed well technically did not advance through regulatory pathways or gain community acceptance. Decision points on deployment often depended on perceptions of risk vs benefit, not only the measured hazard profile.
- Regulatory questions hinge on context. Frow emphasized that risk management frameworks built around laboratory containment become less informative once organisms interact with ecosystems. Instead, risk discourse must consider ecological outcomes, exposure pathways, and monitoring capacity.

At the workshop, these lessons were used to argue for a paradigm shift in how environmental biotechnology is approached: away from an exclusive focus on containment and toward models that recognize and govern living systems in context.

Frow's contribution reinforced the idea that **containment alone cannot be the central organizing principle**. A revealing finding was that containment systems hardly help the perception of safety by potential users, and in some cases they may even do the contrary. Instead, governance must focus on how organisms behave within ecosystems and how their impacts can be **monitored, interpreted and managed over time**.

Rethinking the Regulatory Landscape

The second session shifted toward policy. **Kathleen Lehmann** from the European Commission outlined the evolution of EU GMO legislation. The current framework remains strongly precautionary and historically tied to the techniques of genetic modification. However, recent reforms — particularly around new genomic techniques in plants — signal a gradual move toward more **differentiated and proportionate regulation**.

Future debates are expected to focus increasingly on **microorganisms intended for environmental use**, where the traditional distinction between contained use and deliberate release becomes blurred. One key step in that direction is the ongoing initiative led by the DG – Directorate – Unit SANTE of the EC to streamline authorization procedures for what could be called *low-risk genetically modified microorganisms* with the purpose of simplifying the placing on the market of such microbes in sectors other than food and feed while maintaining high safety standards

From a conservation perspective, **Margret Engelhard** emphasized that ecological systems are complex, adaptive and often poorly understood. Risk assessment must therefore extend beyond the properties of the engineered organism to consider **ecosystem-level interactions, cascading effects and long-term dynamics**.

Finally, Christoph Tebbe explained how soil ecology must inform the safe and effective use of laboratory-trained bacteria for bioremediation. He emphasized the extreme complexity and diversity of soil microbiomes, highlighting the limited scope of current culturable model organisms. Key lessons stress that pollutant degradation is constrained by substrate desorption, nutrient balance, and microbial social interactions. Uneven supplementation may divert metabolism or generate toxic intermediates. Of note is that bioremediation can create new environmental risks related to mobility, toxicity, and carcinogenicity of pollutants through microbial transformation into noxious side-products. Sustainable solutions require managing microbial growth, tailoring strains to local conditions, optimizing enzyme systems, and integrating sociomicrobiology and metagenomics—all of which can be improved with modern molecular breeding. Finally, the presentation underscored the importance of merging environmental risk assessment with “safe-by-design” strategies, and combined pre- and post-market monitoring.

A Shift in Governance Thinking

The concluding discussion brought scientific and policy strands together. Participants broadly agreed that the central regulatory challenge is no longer simply **whether an organism is genetically modified, but how it behaves, where it acts and for how long**.

Different applications — seasonal agricultural inoculants, long-term bioremediation agents, or consumer-facing microbial products — imply fundamentally different exposure patterns and ecological interactions. This diversity strains regulatory systems built on uniform categories.

Across perspectives, there was strong support for moving toward governance models based on:

- **Function and ecological context**, rather than solely on modification technique
- **Monitoring and traceability**, rather than assumptions of permanent containment
- **Adaptive management**, capable of responding to new scientific evidence over time

Environmental biotechnology was framed not only as a technical field, but as a **societal project** requiring transparency, dialogue and trust.

Conclusion: A Governance Transition

The workshop highlighted a field in transition. Laboratory-trained bacteria hold significant promise for tackling pollution, climate-related challenges and ecosystem degradation. At the same time, their use outside controlled environments forces a reconsideration of long-standing biosafety and regulatory assumptions.

The emerging consensus is not to lower safety standards, but to modernize governance: to complement precaution with **proportionality, ecological understanding and long-term stewardship**.

In this sense, the conversation is moving beyond the question of whether engineered microorganisms should ever leave the laboratory, toward a more nuanced and pressing one: **how to manage them responsibly once they do**.

NYPHE 
WORKSHOP
BEYOND GMOs

POLICY, REGULATORY AND SCIENTIFIC ASPECTS ON THE USE OF LABORATORY-TRAINED BACTERIA FOR ENVIRONMENTAL APPLICATIONS

